



# **U.S. Military Smallpox Vaccination Program**

Science – Care – Quality – Confidence

**Armed Forces Epidemiological Board**

*17 September 2003*

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U.S. Army Medical Command



# ***DoD Smallpox Vaccination Policy***

- Announced by President Bush, 13 Dec 02.
  - Vaccinate troops before an attack to ensure they are personally protected and can continue their missions.
- Stages:
  - Stage 1a: Smallpox Epidemic Response Teams (SERTs).
    - 2,000 to 5,000 people, began mid-Dec 02
  - Stage 1b: Medical Teams for Hospitals & Large Clinics.
    - 10,000 to 25,000 people, began early Jan 03
  - Stage 2: Mission-Critical Forces, especially CENTCOM.
    - About 500,000 troops, began early Jan 03

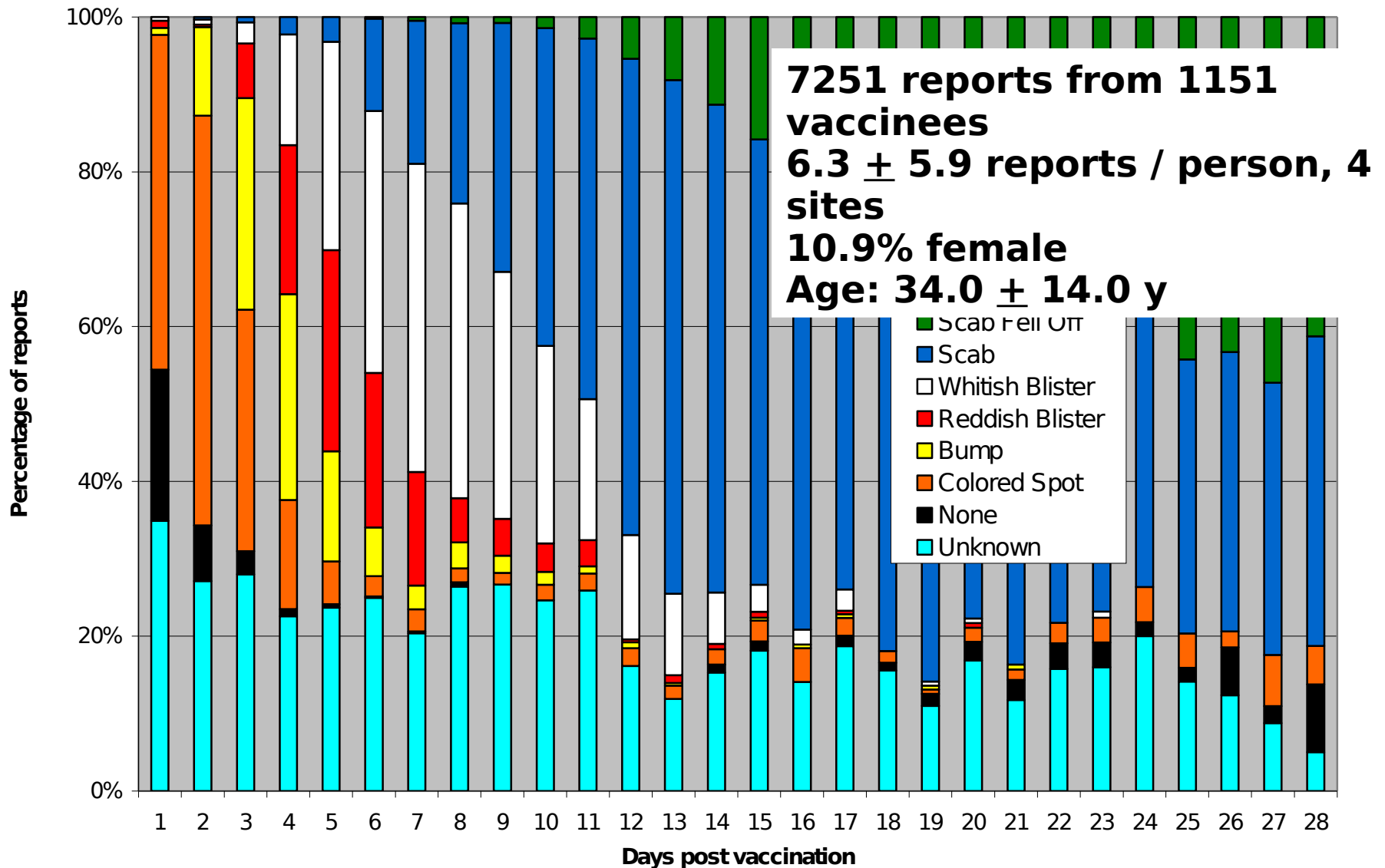


# ***DoD Smallpox Vaccination Program as of 11 Sep 03***

- Response teams, hospital workers, operational forces  
Screened: 565,000      Vaccinated: 492,716
- Primary: 71%      Male: 87%
- Exemption rates vary by location:
  - Personal: 5% to 10%
  - Personal + household: 20% to 30%
- Take (3 sites):
  - Primary, 3 jabs: 96%      Revaccination, 15 jabs: 96%
- Adverse Events: Expected temporary symptoms.
  - Sick leave: Average: 1.5 d
    - Hospital staff: 3% Primary--5.5%      Revax—1.5%
    - Deployed troops: 0.5%



## Vaccinee description of vaccination sites - percentage of reports submitted





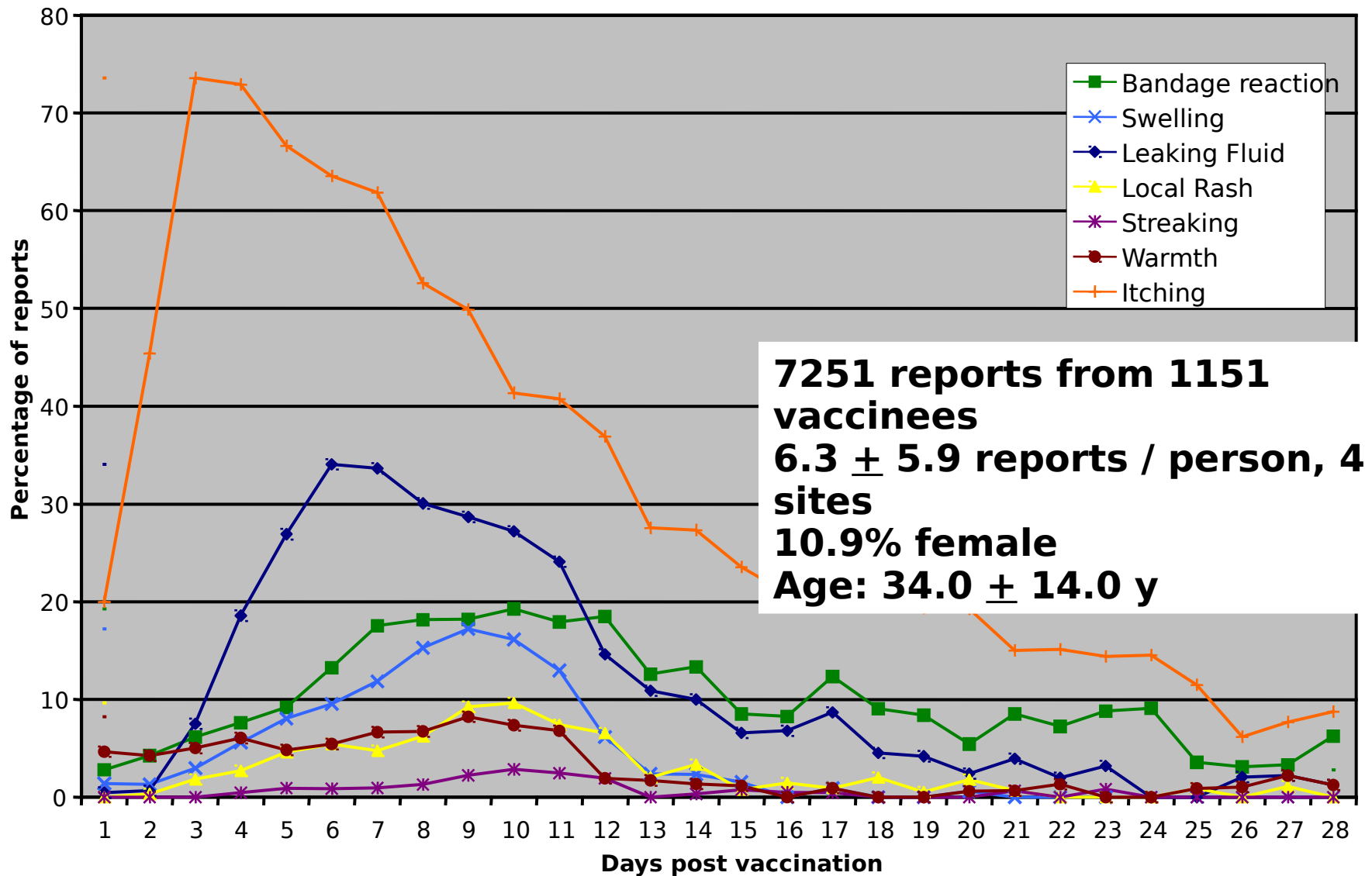
# *Symptoms After Smallpox Vaccination*

Day 6-8, "Take Check," symptoms since vaccination, n = 526, Jan-Feb 2003

- |                       |      |                    |      |
|-----------------------|------|--------------------|------|
| • Local itching       | 60%  | Muscle ache        | 21%  |
| • Feeling lousy       | 20%  | Lymph nodes swell  | 14%  |
| • Headache            | 18%  | Bandage reaction   | 7.4% |
| • Itchy all over      | 5.5% | Fever (subjective) | 5.3% |
| • Local rash          | 5.3% | Body rash          | 1.1% |
| • Eye infection       | 0.0% |                    |      |
| • Restricted activity | 1.3% | Took medication    | 17%  |
| • Outpatient visit    | 0.8% | Limited duty       | 0.0% |
| • Missed work         | 0.2% | Hospitalized       |      |
|                       | 0.0% |                    |      |

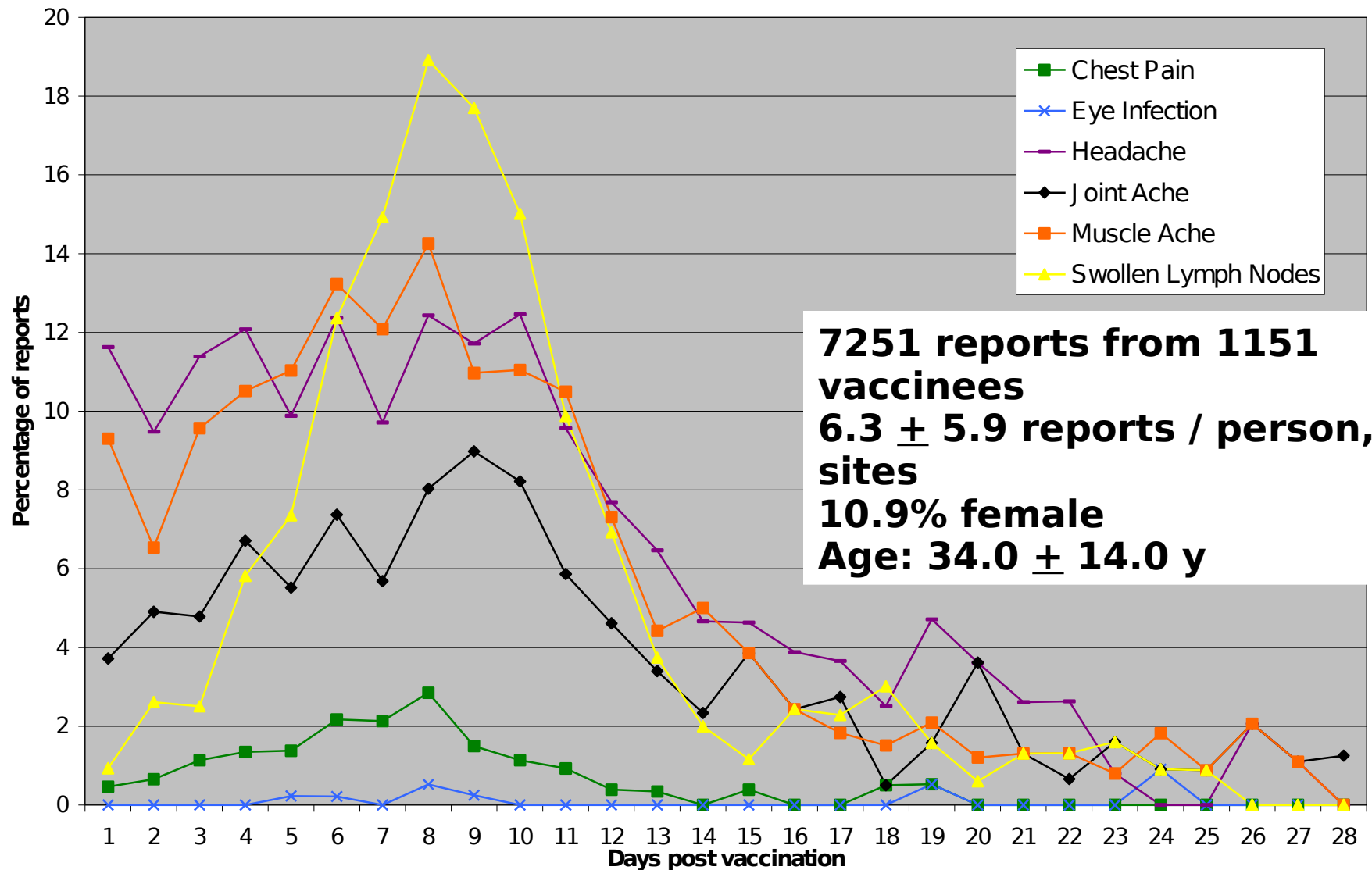


## Percentage of reports describing local symptoms





## Percentage of reports describing systemic symptoms





# ***Screening Before Smallpox Vaccination***

***11 Sep 03***

***n =4,903***

DoD INITIAL MEDICAL NOTES	Self	Contact
No restriction	3,858	3,078
Pregnancy	30	136
Skin condition	149	208
Relevant allergy	43	
Other / unsure	100	59
Immune suppression	32	48
Heart condition	n/a	n/a
Primary Vaccinees	3,268	Further analyses planned
Revaccinees	1,416	
Deferred pending consult, lab	43	
Deferred, temporary contraindication	363	
Contraindicated unless exposed	92	
Vaccination not given, other	24	



# ***DoD Smallpox Vaccination Program as of 11 Sep 03***

- Noteworthy Events among 490,219 Vaccinees:
  - Encephalitis— 1—recovered
  - Generalized vaccinia— 33, all mild, all recovered
  - Inadvertent infection—Skin: Self—48, Contact—27
  - Inadvertent infection—Eye: Self—11, Contact— 2
  - Contact transfer:
    - Family—14, intimate contact—7, friend—8, patient—0
  - Vaccinia Immune Globulin (VIG) treatments: Burn-1, eye-1
  - Myo-pericarditis: Suspect—0, probable—54, confirmed—2
  - Eczema vaccinatum: zero Progressive vaccinia: zero
  - Deaths: Attributed to vaccine: 0 Not attributed to vaccine: 3



# ***DoD Smallpox Vaccination Program***

## ***Myo-pericarditis cases, as of 11 Sep 03***

- People vaccinated: 492,716
- Myo-pericarditis: Suspect—0, probable—54, confirmed—2
- Of the first 18 cases: *JAMA* 2003;289:3283-89
  - Onset interval: 7 to 19 d.
  - Male: 18/18      Age: 21 to 33 years
  - Primary vaccination: 18/18      Present with chest pain: 18/18
  - Enzymes elevated: 18/18      ECG—ST changes: 16/18
  - Echo—abnormal: 10/18      Recover: 18/18, following-up
  - Relative risk: 3.6 for a 30-day interval (95% CI: 3.3, 4.1)
- Conclusion: Smallpox vaccination appears to increase risk of my pericarditis among adult male primary vaccinees.



## ***Myo-pericarditis Case Follow-Up***

- Thru 31 Jul 03
- 52 males, 1 female, aged 21 to 43 years
- confirmed (1 male; 1 female); probable (51 males)
- Primary vaccination: 50/53
- Incidence: 15.36/100,000 primary vaccinees,
  - Relative risk = 7.1 (6.6, 8.1)
- 35 (67%) available for comprehensive follow-up,  $8 \pm 6$  w.
  - 28 (80%) report complete clinical recoveries
  - 22 normal resting echocardiography
  - 13 normal stress exercise testing
  - 2 (6%) persistent non-specific resting ECG changes
  - 7 (20%) persistent subjective symptoms (eg, chest pain).



# ***Early Pregnancy Outcomes Among Women***

***Exposed to Smallpox Vaccine in Pregnancy***

National Smallpox Vaccine in Pregnancy Registry  
Margaret Ryan, DoD Birth and Infant Health Registry

Jane Seward, Kristin Kenyan, Joseph Mulinare, CDC, and others

149 military women registered with vaccinia exposure.

- Age: mean 23 y (range: 18-41y). First pregnancy for 63%.
- 40% vaccinated before conception.
- 28% vaccinated after conception, but before pregnancy test could be +
- 32% vaccinated after 4 weeks gestational age

Among 149 pregnancies:

- 129 progressed to 2<sup>nd</sup> trimester
- 13 had spontaneous abortion (miscarriages)
- 5 had elective abortions
- 2 had ectopic pregnancies

Miscarriage rate: Observed: 8.7% to 9.5%. Expected: 9% to 12%.

Ectopic rate: Observed: 1.3%. Expected: 1% to 2%.



# ***Contact Transfer of Vaccinia Virus as of 11 Sep 03***

- Dec 02 -- Sep 03, 492,716 people vaccinated
- Skin—27, Eye— 2
- Family—14, adult intimate contacts—7, 'sport' partners—6, other friends—2, patient—0
- CO (4), TX (4), NC (4), AK (2), CA (2), CT (1), KS (1), LA (1), OH (1), WA (1), WV (1), overseas (7).
- Viral culture and/or PCR positive: 19 cases; others not tested
- Incidence rate: 5.9 per 100,000 vaccinees overall
  - or 8.4 per 100,000 primary vaccinees.
  - Historical rate: 2 to 6 per 100,000 primary vaccinations.
  - Today: Less immunity among general population.
- Conclusion: Principal risk is to people who share the same bed.
  - Second: Failure to use bandages according to instructions.



# ***Military Vaccination vis-à-vis Pneumonia***

	Rate of hospitalization per 10,000 people per year	95% Confidence Interval
U.S. Army active-duty personnel, worldwide, 2002	10.3	9.3 to 11.1
U.S. Army active-duty personnel, excluding basic training posts, 2002	5.0	4.3 to 5.7
U.S. Army, anthrax- vaccinated only, Dec 02 to Jul 03	2.4	0.8 to 5.5
U.S. Army, smallpox- vaccinated only, Dec 02 to Jul 03	3.0	0.1 to 16.5
U.S. Army, both anthrax- and smallpox-vaccinated only, Dec 02 to Jul 03	3.3	1.9 to 5.2

Source: Defense Medical Surveillance System, 5 Sep 03  
Based on ICD-9-CM codes 480 through 487 for pneumonia and influenza.

Based on personnel reflected on 3<sup>rd</sup> PERSCOM deployment roster.



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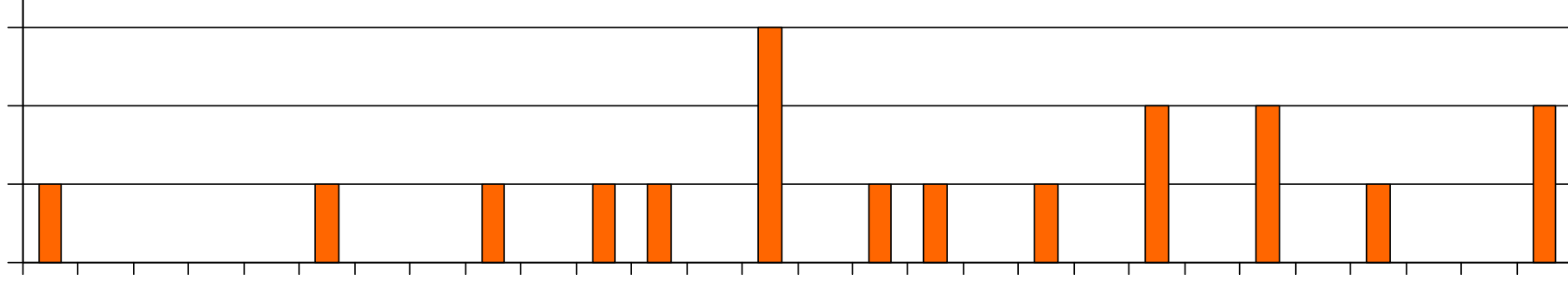
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 **#of Ventilator Cases**

Data as of 8 Sep 03. Investigative team  
still in the field collecting data.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25  
unvax

**Weeks between smallpox  
vaccination and pneumonia  
admission**





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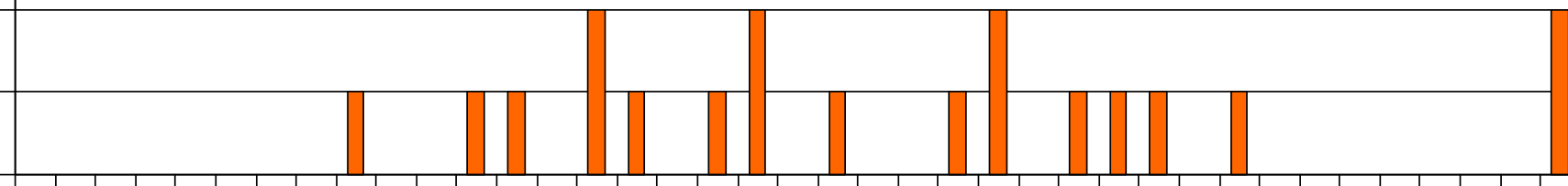
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■ #of Ventilator Cases

Data as of 8 Sep 03. Investigative team still in the field collecting data.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 40-199 >200 unVax

Weeks between first anthrax vaccination and pneumonia admission





■ #of Ventilator Cases

Data as of 8 Sep 03. Investigative team  
still in the field collecting data.

post diag 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31-176 unvax

**Weeks between most recent anthrax  
vaccination and pneumonia admission**

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## ***Vaccinia Lessons Learned***

- Careful screening reduces adverse events  $<$  or  $=$  1960s levels.
  - VIG needed less frequently than expected.
- Education and screening are rate-limiting steps.
- 3 or 15 jabs yield high “take” rates.
- Clinicians ‘alarmed’ by first (maculopapular) rashes they saw in vaccinees; lessened with experience.
- Secondary spread of vaccinia: greatest risk is to bed partners.
- Myo-pericarditis is greater risk than anticipated, principally male, primary vaccinees in DoD’s experience.



# ***Response to AFEB Evaluation of 18 Feb 03***

## **Observation**

## **Response**

Uniform implementation of documentation (6.d) (6.l)

Plan  
-  
ning

Services responsible for audits. Audits being coordinated with DoDIG.

Analyze short-term follow-up data (6.f) (6.h)

✓

4,903 notes analyzed, 526 symptom survey, Voxiva temporal trends for adverse events.

Studies evaluating effectiveness of health risk-communication program (6.f)

✓

CHPPM report provided; data from all three Services.

Plans for long-term evaluation of chronic and subjective outcomes (6.f)

✓

DMSS database analyses by AMSA. Millennium Cohort Study by NHRC. Flight physicals by USAARL. Disability discharges by USARIEM.

Electronic inpt and outpt med rcds in theater (6.f)

✓

Selected data: GEMS > SAMS. Eventually to be relayed to DMSS. MEDEVAC database ✓.

DoD to encourage participation in pregnancy registry (6.f)

✓

Multiple channels: 28 Feb satellite broadcast, OBs+FPs, MILVAX listserv, Service messages, website, *MMWR*

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[THE VACCINE](#)
[THE PRIORITY](#)
[THE STRATEGY](#)
[adverse event info](#)
[education toolkit](#)
[resource center](#)

## SMALLPOX VACCINATION PROGRAM

[contact us](#)


- Smallpox is contagious, deadly, and would disrupt military missions.
- Smallpox vaccine prevents smallpox and we will use it carefully.
- Preserving the health and safety of our people is our top concern.
- The Defense Department's smallpox vaccination program is part of our national strategy to safeguard Americans against smallpox attack.

# MIL VAX

[Program](#)   [SVP Online Proficiency Training](#)   [DoD's Smallpox Vaccination Lessons Learned](#)   [MMWR-Vaccinia Adverse Reactions](#)
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